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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,847	03/27/98	BAY S	102.166A

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EXAMINER	
WESSENDORF,T	
ART UNIT	**PAPER NUMBER**
1627	13

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic(s)
09/049,847	Bay et al
Examiner	**Group Art Unit**
T. Wessendorf	1627

☒ Responsive to communication(s) filed on *Feb 2, 1900*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-14 and 17-25* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14 and 17-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The amendment and REMARKS submitted on 2/20/2000, Paper 12 (page 6) requested cancellation of pages 31-34 of the specification containing a list of references but failed to cancel page 35 which is the last page of said list of references. Correction is required.

New formal drawings are required in this application because of the reasons set forth in PTO 948. The requirement is maintained since applicants have not submitted the formal drawings.

The abstract of the disclosure is objected to because of the inclusion of the phraseology often used in the claims, for example, "comprising". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

A). There is no Sequence Identifier No. for the sequence KLFAVWKITYKDT at page 28, lines 22 and 26. Since applicants have not assigned a Sequence ID. No. for this sequence, the objection to the disclosure is maintained. Applicants are requested to check for other sequences in the specification that have not been assigned an ID No.

The use of the trademark TWEEN 20 at page 21, line 17 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Applicants have indicated that all the trademarks have been capitalized. However, the amendments did not include said corrections.

The rejection of the claims under 35 U.S.C. 112, second paragraph has been withdrawn in view of the amendments to the claim, as indicated by applicants at page 7, paragraphs 2-3 of the instant REMARKS. However, the rejection of claims 22 and 23 under this statute is maintained since contrary to applicants' argument the phrase, "in particular" when used in combination with the phrase "and/or" has not been amended or deleted.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-14 and 17-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-14 24-29 and 33-36 of copending Application No. 09/405,986(the '986 application). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The instant peptide conjugate is identical to the peptide conjugate of the '986 application containing the same components.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-14 and 17-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Bay et al.

Bay discloses at pages 620-624 a peptide conjugate comprising of a carrier comprising a dendrimeric poly-lysine to which a synthetic T cell epitope peptide (T-cell epitope of the VPI protein of poliovirus type 1, the 103-115 region) is linked thereto and a synthetic carbohydrate moiety of defined chemical structure (e.g., Tn antigen) linked to said peptide. The specific peptide conjugate, composition and method of administration to treat tumors therefore fully meet the instant claimed invention.

Claims 1-5, 12-13, 17-18 and 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Chong et al (5,679,352).

Chong discloses at e.g., Figure 1; col. 5, line 29 up to col. 17, line 2; a peptide conjugate comprising of a carrier comprising a dendrimeric poly-lysine to which a synthetic T cell epitope peptide (e.g., Hemophilus influenzae) is linked there to and a synthetic carbohydrate moiety of defined chemical structure (e.g., polyribosyl ribitol phosphate or its repeating units) linked to said peptide. The specific peptide conjugate of Chong therefore fully meets the broadly recited peptide conjugate.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9, 12-14, 17-18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong in view of Zanini et al (Bioconjugate Chemistry).

Chong is discussed, supra. Chong does not disclose that he carbohydrate are tumor antigens. Chong however discloses at e.g., col. 17, lines 27-31 that the synthetic glycoconjugate may be use as vaccines to induce immunity toward tumor cells or to produce antitumor antibodies that can be conjugated to bioactive agents. Zanini positively discloses a conjugate of dendrimeric and a tumor antigen that results in the amplification of the carbohydrate antigen-protein interaction. See e.g., the abstract at page 187. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was

made to conjugate a tumor antigen carbohydrate in the multiple antigen peptide of Chong, not only because Chong suggested such effect of a conjugate to tumors but also, for the advantage taught by Zanini, supra.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong in view of Zanini et al as applied to claims 1-6, 9, 12-14 and 17-25 above, and further in view of Fung et al(Cancer Research).

Chong does not disclose the polysaccharide as containing galactose residue as claimed in claim 6, specifically the 4-α-galactosyl-N acetyl-Ser residues as in claim 7. However, Fung discloses e.g., at page 4308, col. 1 up to page 4313 synthetic polysaccharide tumor antigen containing 4-α-galactosyl-N acetyl-Ser residues attached to protein Keyhole limpet hemocyanin. The said tumor antigen is considered to be an important human tumor marker against which an antitumor immune response could be induced. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the polysaccharide antigen in the conjugate of Chong with a polysaccharide antitumor antigen as the galactosyl containing residues since said carbohydrate antigens when conjugated to a carrier has been shown to be an important human tumor marker

against which an antitumor immune response could be induced, as taught by Fung.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong et al in view of Zanini and Fung and further in view of Tam [5,229,490(I) or 5,580,563(II)).

Chong fails to disclose a peptide-carbohydrate conjugate with the T epitope as being a VP1 protein of poliovirus type 1 as claimed in claim 10 or CD8+T cell epitope as recited in claim 11. However, Tam (I) discloses e.g., at col. 6, lines 10-50; col. 7, Table 1 up to col. 8, line 8 and col. 9, lines 4-18 that conjugates with several identical or different antigenic products of T-cell antigens and B-cell antigens joined to a dendritic polylysine would generate extremely high antibody titers and positively discloses at col. 7, Table 1, lines 25-26 a poliovirus as one of the antigenic products. Tam (II) basically discloses e.g., at col. 5, line 25 up to col. 6, line 4 a similar conjugate as Tam (I). Tam(II) further discloses e.g., at col. 12, lines 44-49 that a dendrimeric polylysine peptide conjugate elicits CD8+ T-cell responses against the gp 160 of HIV. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute poliovirus T-cell peptide antigen as the peptide antigen in the conjugate of

Chong since Tam(I) positively teaches conjugation of said poliovirus to the polylysine and that the said conjugate would expectedly elicit high antibody titers against the virus, as with any antigen containing the polylysine carrier. Likewise, it would have been obvious to use CD8+ as the T-cell epitope peptide antigen as the peptide antigen in the conjugate of Chong since Tam (II) discloses that CD8+ lyses synegenic cells of the gp160 HIV which neutralizes the infectivity of said HIV that will lead to the development of synthetic HIV vaccine. It would be prima facie obvious to select the type of antigen that can be attached to the polylysine as per the suggested teachings of Tam (I) that different kinds of antigen can be attached to the polylysine and provides a list of some of these antigenic determinants.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ponpipom et al discloses a cell specific glycopeptide ligands.

No claim is allowed.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith MacMillan, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

4/20/00

T. Wessendorf

Patent Examiner